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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,876	11/18/2000	John E. Edwards JR.	259/064	7636

34313 7590 09/20/2005

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,876	EDWARDS ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 August 0105* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *091405*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

RESPONSE O APPLICANTS' AMENDMENT

Applicants' Amendments

1) Acknowledgment is made of Applicants' amendments filed 08/01/05 and 07/05/05 in response to the non-final Office Action mailed 04/01/05. With this, Applicants have amended the specification.

Status of Claims

2) Claims 1, 9, 10 and 12 have been amended via the amendment filed 07/05/05.

Claims 1, 3 and 9-12 are pending and are under examination.

Formal Drawings

3) Acknowledgment is made of Applicants' submission of formal drawings filed 08/01/05.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

6) The objection to the drawings made in paragraph 5 of the Office Action mailed 04/09/03 and maintained in paragraph 7 of the Office Action mailed 02/18/04, paragraph 5 of the Office Action mailed 09/15/04, and paragraph 6 of the Office Action mailed 04/01/05 is withdrawn in light of Applicants' submission of formal drawings filed 08/01/05.

7) The objection to claims 3 and 11 and claims 9 and 12 as being duplicate claims encompassing the same scope is withdrawn in light of Applicants' amendments to claims 9 and 12.

Rejection(s) Withdrawn

8) The rejection of claims 10 and 11 made in paragraph 14 of the Office Action mailed 09/15/04 and maintained in paragraph 11 of the Office Action mailed 04/01/05 under 35 U.S.C §

102(b) as being anticipated by Hoyer *et al.* (*J. Bacteriol.* 180: 5334-5343, October 1998, already of record) as evidenced by Harlow *et al.* (*In*: *Antibodies*: *A laboratory Manual.* Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988, already of record), is withdrawn in light of Applicants' amendment to the claims.

9) The rejection of claim 1 and those dependent therefrom made in paragraph 12 of the Office Action mailed 04/01/05 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claim.

10) The rejection of claim 1 made in paragraph 13(a) of the Office Action mailed 04/01/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claim 12 made in paragraphs 13(b) and 13(d) of the Office Action mailed 04/01/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claims 9 and 12 made in paragraph 13(c) of the Office Action mailed 04/01/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

13) The rejection of claims 3, 9 and 11 made in paragraph 13(d) of the Office Action mailed 04/01/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

14) Claims 1, 3 and 9-12 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 1 and 10 are vague, indefinite and confusing in the recitation: 'N-terminal fragment of .... ALS1 .... protein (SEQ ID No. 8)', because it is unclear whether SEQ ID NO: 8 represents the amino acid sequence of the 'N-terminal fragment' or the amino acid sequence of the 'ALS1 protein' itself. It is further unclear whether the parenthetical recitation '(SEQ ID No. 8)' means that the recited fragment or the recited protein comprises or consists of SEQ ID NO: 8.

(b) Claims 1 and 10 are vague and indefinite in the recitation 'effective immune response' because 'effective' is a relative term. The term 'effective' is not specifically defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the claim. What degree of immune response qualifies as an 'effective' immune response, and what element the immune response is effective to, is unclear.

(c) Claims 1 and 10 are vague and indefinite in the limitation: 'effective immune response in a patient'. Since the 'composition' (as opposed to the N-terminal fragment) is recited as producing the immune response, to what element in the composition is the immune response specific to, is not clear. Is the immune response directed to the N-terminal fragment, the ALS1 protein, or the recited *Candida albicans*?

(d) Claims 1 and 9 are incorrect in the limitation 'SEQ ID No.'. To be correct and consistent with the limitation in claims 10 and 12, it is suggested that Applicants replace the limitation with --SEQ ID NO:--.

(e) Claims 3, 9, 11 and 12, which depend from claim 1 or claim 10, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

15) Claims 1 and 3 are rejected under 35 U.S.C § 102(b) as being anticipated by Kraus *et al.* (*J. Immunol.* 139: 3084-3090, 1987).

It is noted that claim 1 includes the open-ended transitional language 'comprising' which does not exclude additional, unrecited N-terminal fragment elements. The transitional term 'comprising' or 'containing' is synonymous with 'including' or 'characterized by' is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (*Fed. Cir.* 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (*CCPA* 1981); *Ex parte Davis*, 80 USPQ 448, 450 (*Bd. App.* 1948) ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). See MPEP 2111.03 [R-1].

It is further noted that the 'N-terminal fragment' recited in claim 1 has no structure or size limit. Therefore, even a single amino acid residue from SEQ ID NO: 8, such as a synthetic or

commercially available cysteine, or a dipeptide from SEQ ID NO: 8, qualifies as an isolated and purified N-terminal fragment of SEQ ID NO: 8. The N-terminal fragment as recited currently is not required to produce 'an effective immune response in a patient', but the pharmaceutical composition is. As presented currently, the recited 'immune response' is not specific to an element or to any specific microorganism, and therefore encompasses any generic 'immune response' produced by the pharmaceutical composition. Furthermore, the N-terminal fragment is not required to contain an adhesion binding site of *C. albicans,* but the protein is.

Kraus *et al.* taught a pharmaceutical composition comprising an adjuvant (i.e., a biocompatible carrier for injection) and a cysteine residue (see paragraph bridging the two columns on page 3085; and first full paragraph in right column on page 3085). The cysteine residue qualifies as an isolated and purified N-terminal fragment of SEQ ID NO: 8 of *C. albicans*, because the prior art cysteine residue constitutes an N-terminal fragment situated at position 73 of the instantly recited SEQ ID NO: 8. The prior art pharmaceutical composition produces an effective immune response in a mammal (see page 3087 and paragraph bridging pages 3086 and 3087) and therefore is also expected to have the inherent ability to produce an effective immune response in a human or non-human patient.

The term 'obtained from *C. albicans*' in the claim represents a process limitation. When claims are drawn to a product-by-process, claims are not limited to the manipulations of the recited step(s), but only the structure implied by the steps. MPEP § 2113 states:

> [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)* (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. Applicants have not shown that the alleged difference(s) in the process results in a product that is structurally different from the product of the prior art. In the instant case, Applicants have not shown that the underlying structure of the prior art fragment, cysteine, differs from that of the instantly claimed N-terminal fragment of the amino acid sequence of SEQ ID NO: 8, i.e., cysteine at position 73 of SEQ ID NO: 8.

Claims 1 and 3 are anticipated by Kraus *et al.*

16) Claims 1, 3, 10 and 11 are rejected under 35 U.S.C § 102(b) as being anticipated by Hoyer *et al.* (*J. Bacteriol.* 180: 5334-5343, October 1998, already of record) (Hoyer *et al.*, 1998).

It is noted that claim 1 includes the open-ended transitional language 'comprising' which does not exclude additional, unrecited fragment or elements. The transitional term 'comprising' or 'containing' is synonymous with 'including' or 'characterized by' is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (*Fed. Cir.* 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (*CCPA* 1981); *Ex parte Davis*, 80 USPQ 448, 450 (*Bd. App.* 1948) ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). See MPEP 2111.03 [R-1].

Instant claims 1 and 3, as amended currently, do not define the claimed N-terminal fragment by its structure or amino acid composition, i.e., SEQ ID number, but appears to identify the protein by its SEQ ID number. The claims do not place a size or structure limit on the recited 'N-terminal fragment'. The N-terminal fragment as recited currently is not required to produce 'an effective immune response in a patient', but the pharmaceutical composition is. The term 'effective' is a relative term unassociated with a particular degree of efficacy. As presented currently, the recited 'immune response' is not specific to an element or to any specific microorganism, and therefore encompasses any generic 'immune response' produced by the pharmaceutical composition. Furthermore, the N-terminal fragment is not required to contain an adhesion binding site of *C. albicans,* but only the protein is.

Hoyer *et al.* (1998) taught a composition, which comprises the isolated and purified N-terminal domain of an adhesion protein, Als1p, of *Candida albicans* dissolved in PBS, i.e., a biocompatible carrier for injection or infusion (see pages 5334, 5336 and 5337). Hoyer *et al.* (1998) taught the 65-kDa N-terminal fragment and the amino acid sequencing of this Als1p-derived 'fragment' in the third full paragraph of the left column of page 5336. Hoyer *et al.* (1998) taught the recombinantly expressed N-terminal 433 amino acid-long fragment of *Candida albicans* Als1p expressed via the heterologous host, *Saccharomyces cerevisiae*. See the second full paragraph in the left column of page 5336. The recombinant N-terminal portion of Als1p secreted into the culture supernatant was purified by ammonium sulfate precipitation, centrifuged, the precipitate collected,

dissolved in PBS (i.e., a biocompatible carrier), and thoroughly dialyzed against PBS in a dialysis tubing having a molecular weight cut off of 12,000 to 14,000. The dialysate was concentrated. The resultant product meets the instantly claimed product because it consists essentially of PBS and the isolated and purified 433 amino acid-long N-terminal portion of the Als1p protein in that: (a) the N-terminal portion of Als1p is isolated from the cellular mass of the microorganism; and (b) the recombinantly expressed N-terminal portion of Als1p is purified by ammonium sulfate precipitation followed by centrifugation and dialysis, and therefore is free of other antigens of *Candida albicans*. Due to the multiple purification steps, such as, ammonium sulfate precipitation, centrifugal separation, and dialysis followed by concentration, Hoyer's (1998) N-terminal fragment is more than sufficiently purified for inclusion in a pharmaceutical composition. The purified, dialyzed and concentrated final prior art recombinant N-terminal fragment product contained in PBS qualifies as a pharmaceutical composition comprising a biocompatible carrier. The recitation 'for injection or infusion' in claims 1 and 10 represents the intended use of the product and has no patentable weight. The functional limitation, i.e., production of an effective immune response, on which the prior art reference is allegedly silent, is considered as an inherent property inseparable from the prior art N-terminal protein fragment. Where the only difference between the claimed product and the prior art product is recited in the functional language, i.e., by what it does rather than what it is, it is incumbent upon Applicants, when challenged by the USPTO, to demonstrate that the prior art product does not actually possess those characteristics. Applicants have not established that Hoyer's (1998) isolated and purified 433 amino acid-long 65-kDa N terminal fragment contained in PBS is incapable of producing an effective immune response in a patient. It is well known in the art that a microbial protein fragment as long as the one taught by Hoyer *et al.* (1998) is long enough to serve intrinsically as an effective immunogen, being capable of producing an effective immune response in a patient, absent evidence to the contrary.

The term 'obtained from *C. albicans*' in claims 1 and 10 represents a process limitation. When claims are drawn to a product-by-process, claims are not limited to the manipulations of the recited step(s), but only the structure implied by the steps. MPEP § 2113 states:

> [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)* (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. Applicants have not shown that the alleged difference(s) in the process results in a product that is structurally different from the product of the prior art. In the instant case, Applicants have not shown that the underlying structure of the prior art N-terminal 433 amino acid-long fragment of the ALS1 protein differs from that of the instantly claimed N-terminal fragment of the amino acid sequence of SEQ ID NO: 8.

Claims 1, 3, 10 and 11 are anticipated by Hoyer *et al.* (1998).

Remarks

17) Claims 1, 3 and 9-12 stand rejected.

18) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses or papers is (571) 273-8300.

19) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

20) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2005

S. DEVI, PH.D.
PRIMARY EXAMINER